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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,686	10/12/2000	Juha Kononen	4239 55593	2751

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/26/2002 11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/622,686	KONONEN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *1-25 and 38-50* is/are withdrawn from consideration.

5)☒ Claim(s) *29,31-35,37,54,57 and 60* is/are allowed.

6)☒ Claim(s) *26-28,30,36,51-53,55,56,58,59 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This action is in response to papers filed 29 April 2002 in Paper No. 9 in which claims 27, 29, 30 and 36 were amended and claims 51-66 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 8 dated 19 December 2001 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections of Claims 26, 28, 30 and 36 under 35 U.S.C. 102 (b) over Barrere et al are maintained. The previous rejections of Claims 27, 29, 31-35 and 37 are withdrawn in view of the amendments and arguments. The previous rejections of under 35 U.S.C. 102(b) over Furmanski et al are withdrawn in view of the amendments and arguments. All of the arguments have been thoroughly reviewed and are discussed below as they pertain to the instant rejection. New grounds for rejection are discussed.

Currently claims 26-37 and 51-66 are under prosecution.

Priority

2. Applicant's amendment to the specification citing priority to PCT US99/04001 and Provisional Application 60/622,686 is acknowledged. The amendment has been entered.

Specification

3. Applicant's amendment adding an Abstract to the specification is acknowledged. The Abstract has been entered.

Information Disclosure Statement

4. The references listed on the 1449 of Paper No. 10 have been reviewed and considered.

Restrictions

5. Applicant's election with traverse of Group II in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the corresponding technical feature defines a contribution over Battifora et al. This is not found persuasive because as stated in the previous office action the technical feature linking groups I-IV is considered to be the array for performing an analysis of biological specimens wherein the array comprises donor specimens in a receptacle at fixed assigned locations which are maintained and recorded. Battifora et al teach the array for performing an analysis of biological specimens wherein the array comprises donor specimens in a receptacle at fixed assigned locations which are maintained and recorded (Column 2, line 54-Column 3, line 26). Applicant argues that because Battifora et al do not teach the method of Claim 1, they do not teach the special technical feature linking Groups I-IV. The argument has been considered but is not found persuasive because according to PCT Rule 13.2, it is the linking feature, not Claim 1 that defines the contribution over the prior art. Because Battifora et al teach the technical feature linking Groups I-IV, the technical feature does not define a contribution over the prior art as defined under PCT Rule 13.2.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

7. Claims 26, 28, 30, 36, 51, 59, 61, 64 and 66 are rejected under 35 U.S.C. 102(b) as anticipated by Barrere et al. (U.S. Patent No. 4,684,613, issued 4 August 1987).

Regarding Claim 26, Barrere et al. disclose an apparatus for preparing specimens (i.e. semi-solid media) for parallel analysis of sections of biological material arrays comprising: a donor block holder for holding the donor block; a reciprocal punch positioned in relation to the holder to punch a specimen from the donor block; and a recipient block holder for holding a recipient block in a recipient position, wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position in relation to the reciprocal punch to deliver a specimen from the reciprocal punch into the preselected position (Column 2, lines 1-22 and Fig. 1 and 6). Barrere et al. do not teach their donor block holder is "for holding a tissue donor block" and they do not teach their reciprocal punch is "to punch a tissue specimen from the tissue door block". However, these recitations are functional and do not describe the apparatus in terms of structure. The courts have stated that an apparatus must be distinguished in terms of structure rather than function.

> Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)
>
> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of

the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)(see MPEP, § 2114).

Therefore because Barrere et al. disclose the structural limitations of the apparatus, they disclose the apparatus as claimed.

Regarding Claim 28, Barrere et al. disclose the apparatus further comprising a stylet positioned for introduction into the reciprocal punch to expel the specimen from the punch into one of the receptacles aligned with the punch (Column 3, lines 5-11 and Fig. 2).

Regarding Claim 30, Barrere et al. disclose the apparatus further comprising a separate reciprocal punch capable of being positioned relative to the recipient block wherein the separate punch is different that the reciprocal punch i.e. the separate punch is one of the adjacent punches as illustrated in Fig. 3 which is different from the reciprocal punch in that it is located in an adjacent position (Column 2, lines 65-68 and Fig. 3).

Regarding Claim 36, Barrere et al. disclose the apparatus wherein the recipient block comprises an array of spaced biological specimens in a fixed array (Column 5, lines 30-32, Claim 2 and Fig. 1).

Regarding Claim 51, Barrere et al disclose an apparatus for preparing specimens for parallel analysis of biological material comprising: means for holding a tissue donor block; means for extracting a tissue specimen from the donor block; and means for holding a recipient block in a recipient position wherein the recipient block comprises an array of receptacles each positionable in a preselected position (Column 2, lines 1-22, Column 5, lines 24-38 and Fig. 1 and 6)

Regarding Claim 52, Barrere et al disclose the apparatus wherein the tissue specimen can be delivered from the reciprocal punch into the preselected position (Column 5, lines 24-38).

Regarding Claim 59, Barrere et al disclose an integrated apparatus for preparing specimens for parallel analysis comprising: a donor block holder; a reciprocal punch positioned

in relation to the donor block holder; and a recipient block holder wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position (Column 2, lines 41-55).

Regarding Claim 61, Barrere et al disclose the apparatus further comprising a second and different reciprocal punch (Column 2, lines 65-68 and Fig. 3).

Regarding Claim 64, Barrere et al disclose the apparatus of Claim 26 further comprising z-direction positioning means for the reciprocal punch (Column 2, lines 59-64).

Regarding Claim 66, Barrere et al disclose the apparatus of Claim 59 further comprising z-direction positioning means for the reciprocal punch (Column 2, lines 59-64).

Response to Arguments

8. Applicant argues that Barrere et al teach only one holder i.e. #25 that supports the punch but does not disclose the claimed apparatus comprising two holders. The argument has been considered but is not found persuasive because contrary to Applicant's assertion, Barrere et al do teach two holders, a donor holder and recipient holder, which are positioned on slidble base 10 (Column 2, lines 41-48 and Fig. 1). The holders have been labeled by the examiner to facilitate Applicant's understanding of the above rejection.

Applicant argues that the device of Barrere et al does not include the claimed stylet because the spigot 31 appears to be simply a void within body 27. The argument has been considered but is not found persuasive for numerous reasons. Barrere et al do not teach the spigot, 31, is a void. Therefore, Applicant's assertion that their spigot is a void is considered by the examiner to be speculative because it is not based on the teaching of Barrere et al. Barrere et al do teach that the punch, 32, is fitted over the spigot 31 which communicates with a pipe, 36, at the upper end (Column 3, lines 5-11). The instant claim is drawn to a "stylet positioned for introduction into the reciprocal punch". The spigot and/or the pipe of Barrere

et al are encompassed by the claimed "stylet" because the both are positioned for introduction into the reciprocal punch 32 as claimed.

9. Claims 26-28, 30, 36 and 51-53, 55, 56, 58, 59 and 61-66 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The instantly claimed invention has a common inventor with U.S. Patent No. 6,383,801, filed 19 March 2001. The '801 patent teaches the claimed subject matter and claims the same and/or similar invention. As such it is unclear who invented the instantly claimed invention.

Regarding Claim 26, Leighton discloses an apparatus for preparing specimens for parallel analysis of sections of biological material arrays comprising: a donor block holder for holding the donor block; a reciprocal punch positioned in relation to the holder to punch a specimen from the donor block; and a recipient block holder for holding a recipient block in a recipient position, wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position in relation to the reciprocal punch to deliver a specimen from the reciprocal punch into the preselected position (Claim 1).

Regarding Claim 27, Leighton discloses the apparatus wherein the recipient holder comprises an x-y positioning device that can be incrementally moved to align sequential receptacles and the reciprocal punch (Claims 4-6).

Regarding Claim 28, Leighton discloses the apparatus further comprising a stylet positioned for introduction into the reciprocal punch to expel the specimen from the punch into one of the receptacles aligned with the punch (Claim 1).

Regarding Claim 30, Leighton discloses the apparatus further comprising a second reciprocal punch capable of being positioned relative to the recipient block wherein the second punch is different that the reciprocal punch (Claim 1).

Regarding Claim 36, Leighton discloses the apparatus wherein the recipient block comprises an array of spaced biological specimens in a fixed array (Claim 1 and Column 2, lines 32-58).

Regarding Claim 51, Leighton discloses an apparatus for preparing specimens for parallel analysis of biological material comprising: means for holding a tissue donor block; means for extracting a tissue specimen from the donor block; and means for holding a recipient block in a recipient position wherein the recipient block comprises an array of receptacles each positionable in a preselected position i.e. pocket (Column 5, line 61-Column 6, line 12).

Regarding Claim 52, Leighton discloses the apparatus wherein the tissue specimen can be delivered from the reciprocal punch into the preselected position (Column 6, lines 5-12).

Regarding Claim 53, Leighton discloses the apparatus further comprising an x-y positioning platform coupled to the donor block holder and recipient block holder (Column 5, line 61-Column 6, line 12).

Regarding Claim 55, Leighton discloses a device for preparing biological material arrays comprising: a platform that includes at least one guide for positioning a tissue donor block holder or a recipient block holder; and a punch apparatus that includes a guide surface, a punch base slidably mounted on the guide surface and a punch within the base that can be aligned with the tissue block holder or recipient block holder (Claims 1-6).

Regarding Claim 56, Leighton discloses the device further comprising means for sliding the punch base i.e. drive (Column 5, lines 15-16).

Regarding Claim 58, Leighton discloses an apparatus for preparing specimens for biological material arrays comprising: an x-y positioning platform; a tissue donor block holder disposed on the x-y positioning platform; a recipient block holder disposed on the x-y positioning platform; and at least one reciprocal punch coupled to the x-y positioning platform (Claim 1-8).

Regarding Claim 59, Leighton discloses an integrated apparatus for preparing specimens for parallel analysis comprising: a donor block holder; a reciprocal punch positioned in relation to the donor block holder; and a recipient block holder wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position (Claim 1).

Regarding Claim 61, Leighton discloses the apparatus further comprising a second and different reciprocal punch (Claim 1).

Regarding Claim 62, Leighton discloses the apparatus of Claim 30 wherein the diameter of the first reciprocal punch is greater than the diameter of the second reciprocal punch (Column 1, lines 50-53 and Column 3, lines 24-27).

Regarding Claim 63, Leighton discloses the apparatus of Claim 61 wherein the diameter of the first reciprocal punch is greater than the diameter of the second reciprocal punch (Column 1, lines 50-53 and Column 3, lines 24-27).

Regarding Claim 64, Leighton discloses the apparatus of Claim 26 further comprising z-direction positioning means for the reciprocal punch (Claim 8).

Regarding Claim 65, Leighton discloses the apparatus of Claim 58 further comprising z-direction positioning means for the reciprocal punch (Claim 8).

Regarding Claim 66, Leighton discloses the apparatus of Claim 59 further comprising z-direction positioning means for the reciprocal punch (Claim 8).

10. Claims 26-28, 30, 36, 51-53, 55, 56, 58, 59 and 61-66 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The instantly claimed invention has a common inventor with U.S. Patent No. 6,103,518, filed 5 March 1999.

The '518 patent teaches the claimed subject matter and claims the same and/or similar invention. As such it is unclear who invented the instantly claimed invention.

Regarding Claim 26, Leighton discloses an apparatus for preparing specimens for parallel analysis of sections of biological material arrays comprising: a donor block holder for holding the donor block; a reciprocal punch positioned in relation to the holder to punch a specimen from the donor block; and a recipient block holder for holding a recipient block in a recipient position, wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position in relation to the reciprocal punch to deliver a specimen from the reciprocal punch into the preselected position (Claim 1).

Regarding Claim 27, Leighton discloses the apparatus wherein the recipient holder comprises an x-y positioning device that can be incrementally moved to align sequential receptacles and the reciprocal punch (Claim 1).

Regarding Claim 28, Leighton discloses the apparatus further comprising a stylet positioned for introduction into the reciprocal punch to expel the specimen from the punch into one of the receptacles aligned with the punch (Claim 1).

Regarding Claim 30, Leighton discloses the apparatus further comprising a second reciprocal punch capable of being positioned relative to the recipient block wherein the second punch is different that the reciprocal punch (Claim 1).

Regarding Claim 36, Leighton discloses the apparatus wherein the recipient block comprises an array of spaced biological specimens in a fixed array (Claim 1).

Regarding Claim 51, Leighton discloses an apparatus for preparing specimens for parallel analysis of biological material comprising: means for holding a tissue donor block; means for extracting a tissue specimen from the donor block; and means for holding a recipient block in a recipient position wherein the recipient block comprises an array of receptacles each positionable in a preselected position (Claim 1).

Regarding Claim 52, Leighton discloses the apparatus wherein the tissue specimen can be delivered from the reciprocal punch into the preselected position (Claims 1-4).

Regarding Claim 53, Leighton discloses the apparatus further comprising an x-y positioning platform coupled to the donor block holder and recipient block holder (Claim 1).

Regarding Claim 55, Leighton discloses a device for preparing biological material arrays comprising: a platform that includes at least one guide for positioning a tissue donor block holder or a recipient block holder; and a punch apparatus that includes a guide surface, a punch base slidably mounted on the guide surface and a punch within the base that can be aligned with the tissue block holder or recipient block holder (Claims 1-4).

Regarding Claim 56, Leighton discloses the device further comprising means for sliding the punch base i.e. drive (Column 5, lines 15-16).

Regarding Claim 58, Leighton discloses an apparatus for preparing specimens for biological material arrays comprising: an x-y positioning platform; a tissue donor block holder disposed on the x-y positioning platform; a recipient block holder disposed on the x-y positioning platform; and at least one reciprocal punch coupled to the x-y positioning platform (Claim 1-4).

Regarding Claim 59, Leighton discloses an integrated apparatus for preparing specimens for parallel analysis comprising: a donor block holder; a reciprocal punch positioned in relation to the donor block holder; and a recipient block holder wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position (Claim 1).

Regarding Claim 61, Leighton discloses the apparatus further comprising a second and different reciprocal punch (Claim 1).

Regarding Claim 62, Leighton discloses the apparatus of Claim 30 wherein the diameter of the first reciprocal punch is greater than the diameter of the second reciprocal punch (Column 12, lines 39-42).

Regarding Claim 63, Leighton discloses the apparatus of Claim 61 wherein the diameter of the first reciprocal punch is greater than the diameter of the second reciprocal punch (Column 12, lines 39-42).

Regarding Claim 64, Leighton discloses the apparatus of Claim 26 further comprising z-direction positioning means for the reciprocal punch (Claim 3).

Regarding Claim 65, Leighton discloses the apparatus of Claim 58 further comprising z-direction positioning means for the reciprocal punch (Claim 3).

Regarding Claim 66, Leighton discloses the apparatus of Claim 59 further comprising z-direction positioning means for the reciprocal punch (Claim 3).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 26-28, 30, 36, 51-53, 55, 56, 58, 59 and 61-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,383,801 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus (instrument) for constructing arrays of biological material (tissue) wherein both sets of claims

are drawn to identical structural components i.e. donor block holder, recipient block holder, punch comprising a stylet, positioning means, and x-y-z movement means. The patent and instant claims differ only in the listing order of the claimed structures (e.g. the instant dependent claim 28, is drawn to the apparatus further comprising a "stylet" while the patent independent claim recites "stylet") and terminology used to describe some of the structures (e.g. the instant claims recite "donor block holder" while the patent claims recite "platform for holding"). However, the differing listing order and terminology does not distinguish the instantly claimed invention from that of the '801 patent instrument because both sets of claims define extremely similar apparatus.

13. Claims 26-28, 30, 36, 51-53, 55, 56, 58, 59 and 61-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 17 and 18 of U.S. Patent No. 6,103,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus (instrument) for constructing arrays of biological material (tissue) wherein both sets of claims are drawn to identical structural components i.e. donor block holder, recipient block holder, punch comprising a stylet, positioning means, and x-y-z movement means. The patent and instant claims differ only in the listing order of the claimed structures (e.g. the instant dependent claim 28, is drawn to the apparatus further comprising a "stylet" while the patent independent claims recite "stylet") and terminology used to describe some of the structures (e.g. the instant claims recite "donor block holder" while the patent claims recite "means for holding"). However, the differing listing order and terminology does not distinguish the instantly claimed invention from that of the '518 patent instrument because both sets of claims define extremely similar apparatus.

Conclusion

14. No claim is allowed. Claims 29, 31-35, 37, 54, 57 and 60 are free of the prior art of record and may be placed in condition for allowance following resolution of the above rejections.

15. The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached between 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 24, 2002